

Clarification of Drug Allergy Information Using a Standardized Drug Allergy Questionnaire and Interview

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ABSTRACT

Background: Vague, incomplete, or inaccurate drug-allergy histories can be detrimental to patient safety and affect patient care. There is an increased chance of medication errors if details of a drug allergy are not documented. Incomplete or inaccurate allergy histories may also result in increased time spent by health care providers to clarify an order in question. Published literature from the early 1990s showed that a patient interview can facilitate collection of more complete allergy information and could lead to the removal of a documented drug allergy in approximately one-third of patients.

Purpose: This quality-improvement project was conducted to improve the process of collecting drug-allergy information at our institution.

Description: The primary objective of this project was to determine the number of patients with a clinically relevant change in allergy history after a standardized drug-allergy questionnaire and interview compared with documentation prior to the interview. This was a descriptive, prospective quality improvement project of a standardized drug-allergy questionnaire and interview. Patients were asked about the history of their allergic reaction, including the drug, route, nature of reaction, treatment of reaction, and time since reaction.

Results: A total of 301 patient allergy profiles were reviewed. After screening, 202 patients were included and interviewed, for a total of 509 drug allergies. One hundred twenty-three patients (61%) had a need for a clinically relevant change in allergy history after an interview. A total of 228 changes were made to patient allergy profiles. Adding the allergy reaction accounted for 131 of the changes. Also, there were 185 allergies documented prior to the interview that were categorized as unclear/vague, which was significantly reduced to 112 after the interview ($P < 0.0001$).

Conclusion: More complete drug-allergy information was obtained after executing a standardized drug-allergy questionnaire and interview.

Keywords: patient interview, drug allergy, quality improvement

BACKGROUND

Vague, incomplete, or inaccurate drug-allergy histories can negatively impact patient safety, affect the care of patients, and disrupt the workflow of clinicians. There is an increased

chance of medication error if allergy details are not properly documented.¹ Lack of details surrounding an allergic reaction, especially severe reactions, may cause an allergy to be overlooked or the severity underestimated. Inaccurate or incomplete information about a patient's drug allergies may also result in a change in drug therapy for the patient that may be unnecessary or is less tolerated.² Drug intolerances that are interpreted as drug allergies by the clinician can limit the spectrum of medications that can be used, a problem that is frequently encountered with antimicrobials. A switch to alternative medications may also increase length of stay and cost.^{3,4} Lastly, lack of clear allergy information may result in increased time spent by clinicians to clarify an order in question, which can cause a disruption in workflow. Although primarily thought to affect pharmacists who are inputting or verifying an order, nurses and physicians are often affected as well. Most importantly, such disruptions in workflow may create a delay in the medication reaching the patient.

Previous studies have been performed to clarify patient allergies. However, there are few studies that have used a standardized drug-allergy questionnaire and interview, and these were performed in the early 1990s. The interview component is optimal because patients are presumed to be the best source of information regarding their drug allergies.⁵ A review of the literature found three studies that utilized a patient interview to investigate allergy histories. Tripp et al. found documented drug allergies that could be removed for 169 of the 606 allergies reported (28%) after a pharmacist-conducted patient interview.⁶ Allergies were removed at the discretion of the pharmacist when the reaction reported was not consistent with that of a true allergy. Beta-lactam antibiotics and opioids were the two most common drug classes that patients reported as drug allergies, which accounted for half of the reported allergies overall.⁶ Pilzer et al. also conducted a prospective patient interview that was completed by pharmacists. The aim of Pilzer et al. was to categorize patient drug allergies into "true allergy," "intolerance," or "unknown" using predefined reactions for each category. Pilzer and colleagues found only 13 of the 150 reported allergies actually contraindicated a medication for use as determined by the judgment of the pharmacist.⁷ Cantrill et al. conducted a patient interview in addition to a one-day chart audit to assess proper documentation of drug allergies. The audit found 36% of drug allergies reported were not correctly documented on the patient's chart.⁸ The study also found that 40% of the 78 reported allergies were not considered to be true allergies as set forth by the study's predefined symptom list.⁸ In summary, these three studies demonstrated that completion of a standardized patient interview led to more complete and

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accurate allergy information.

Proper documentation of patient drug-allergy information is essential for every health care facility. Unfortunately, there is no method that is recognized as a gold standard to collect allergy information, and obtaining patient allergy information may be challenging. There are many patient-specific factors that can interfere with obtaining allergy histories, such as age, mental status, or inability to recall the medication and/or reaction.¹ The completeness of the information gathered may be left to the discretion of the clinician, leading to processes that are not standardized from patient to patient at an institution.⁹ Some institutions may also document allergy information in several places, further increasing the chance for discrepancies and confusion.

This project was performed to determine if using a standardized drug-allergy questionnaire and interview provided more clinically useful information compared with the current approach used to obtain allergy information at our institution.

METHODS

This was a descriptive, prospective quality improvement project of a standardized drug-allergy questionnaire and interview used to obtain drug-allergy information at a 511-bed adult community teaching hospital. The project was submitted to the investigational review board (IRB), which deemed it a "Quality Improvement Project," thus not requiring IRB oversight.

Currently, there is no standardized process to gather allergy information at our institution. The nature and degree of detail of the information collected about patient drug allergies is dependent on the clinician obtaining the history, and there is no mandate to describe the allergy reaction. Our institution also utilizes several different sources where allergy information may be documented. The aim of this project was to improve the current process used to gather drug-allergy information at the institution.

Patients included were admitted to a general medical or surgical floor with one or more reported allergies. Patients were excluded if they were younger than 18 years of age, had allergies only to nonmedications, refused to participate, were not in their room at the time of interview, were previously interviewed during the project period, or had insufficient mental alertness or cognitive ability to reliably answer questions as determined by the interviewer.

The standardized drug-allergy questionnaire and interview was conducted by the same PGY-1 pharmacy resident from November 2014 to February 2015. Patients admitted within the previous 48 hours to a general medical/surgical floor with at least one documented allergy were identified daily by the use of clinical-decision-support software. The decision to include only patients with at least one documented drug allergy was done in an effort to filter higher risk patients in the timeframe available. A random number generator was used for patient selection to reduce bias from the identified patients. Once the patient was selected, the interviewer screened for exclusions by reviewing the patient's medical records. If deemed eligible by review of records, the interviewer would then go to the patient's room and confirm that the patient was sufficiently alert and oriented to person, place, and time. A seven-question questionnaire was then administered to the selected patient

Figure 1 Patient Drug Allergy Assessment Questionnaire

1. Have you ever taken any medication(s) that have caused a reaction?
☐ Yes ☐ No
☐ Needed Prompting: ☐ Yes ☐ No
2. Describe the reaction you had.
☐ True Allergy:
☐ Anaphylaxis ☐ Shortness of Breath
☐ Other: _____
☐ Hives ☐ Angioedema
☐ Itching ☐ Rash/Other Serious Skin Reaction

☐ Intolerance/Adverse Effect:
☐ Dizziness ☐ Muscle Pain/Soreness ☐ Stomach Upset/Pain
☐ Drowsiness ☐ Nausea ☐ Vomiting
☐ Headache ☐ Swelling (Other) ☐ Diarrhea
☐ Weakness ☐ Other: _____
☐ Unclear/Vague
☐ Needed Prompting: ☐ Yes ☐ No
3. How did you take this medication?
☐ Inhaled ☐ Injection ☐ By Mouth ☐ On the Skin
☐ Other: _____
☐ Needed Prompting: ☐ Yes ☐ No ☐ Unclear/Vague
4. How soon after starting the medication did the reaction happen?
☐ ___Hours ☐ ___Days ☐ ___Weeks ☐ ___Months ☐ ___Years
☐ Needed Prompting: ☐ Yes ☐ No ☐ Unclear/Vague
5. How long ago did this reaction happen?
☐ < 5 years ago ☐ 5–10 years ago ☐ > 10 years ago
☐ Needed Prompting: ☐ Yes ☐ No ☐ Unclear/Vague
6. Did you seek medical attention for the reaction?
☐ Yes ☐ No
- 6a. Were you seen in the
☐ ED ☐ Doctor's office
☐ Already in hospital ☐ Hospital admission
- 6b. Was the medication stopped by a doctor?
☐ Yes ☐ No ☐ Unclear/Vague
7. Have you ever taken this medication or a similar one again?
☐ Yes ☐ No ☐ Unclear/Vague
- 7a. If yes, did you experience the same problem?
☐ Yes ☐ No

(see Figure 1). Patients were asked about their history of drug reactions and drug, route, nature of reaction, treatment of reaction, and time since reaction. If a patient was unable to recall information for a given question, the patient could be prompted with predetermined prompts (i.e., time since reaction: less than five years ago, five to 10 years ago, or more than 10 years ago). It took the interviewer an average of 10 minutes to complete one drug-allergy questionnaire and interview. Patient drug-allergy histories were updated as needed based on information obtained from the patient interview. Of note, the patient's physician was contacted prior to removing documentation of an allergy.

The primary outcome was the proportion of patients with a clinically relevant change in drug-allergy history after completing a standardized drug-allergy questionnaire and interview. A clinically relevant change was defined as an allergy and/or associated reaction added to or removed from the patient's documented allergy history after the interview.

Several secondary outcomes were also examined. The patient's reported reaction to each drug was categorized by the investigator as "true allergy," "adverse effect," or "unclear/vague" (Table 1). (Definitions were created by the authors

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Table 1 Definition of Allergy Categories in Project

True allergy	Patient reported symptoms consistent with immunological drug allergy, including but not limited to anaphylaxis, hives, itching, shortness of breath, swelling, rash/other serious skin reactions, or any other serious reaction where the drug or drug class would not be used again as determined by the investigator.
Adverse effect	Patient reported symptoms that are not consistent with immunological drug allergy, including but not limited to nausea, vomiting, diarrhea, dizziness, headache, drowsiness, weakness, chest pain, agitation, or any other reaction where the drug or drug class could be used again if needed as determined by the investigator.
Unclear/vague	Patient could not recall the reaction or the symptoms were not sufficiently descriptive to allow for classification, so a true allergy cannot be ruled out.

using the reactions listed in similar trials). Categorization of the reaction was done once before and once after the interview based on the description of the reaction available. The number of allergies in each category before and after the standardized patient interview was a secondary outcome (Figure 2). The association of certain patient characteristics with the need for a clinically relevant change to the documented drug-allergy history was also determined. The patient characteristics investigated included age, gender, number of documented home medications, number of reported drug allergies prior to the interview, and number of inpatient admissions to the institution in the previous 12 months.

STATISTICAL ANALYSIS

Descriptive statistics were utilized for primary and most secondary outcomes. Relative risk (RR; 95% confidence interval [CI]) was calculated to determine the association between patient characteristics and clinically relevant change in drug-allergy history. Patient characteristics that were evaluated included gender, age older than 65 years, at least one hospitalization in the facility in the previous 12 months, more than five reported home medications, and more than three reported drug allergies at baseline. *Chi-square* was used to compare the difference in the proportion of allergies categorized as unclear/vague before and after the standardized drug-allergy questionnaire and interview. Statistics were calculated using Microsoft Excel.

RESULTS

A total of 301 patient-allergy profiles were reviewed. After screening, 202 patients were included and administered the drug-allergy assessment questionnaire and interview. A total of 509 drug allergies were reported by the included patients. The two most common types of medications that patients reported as allergies were analgesics (37% of total reported allergies) and antibiotics (34% of total reported allergies). Oral medications accounted for 66% of the allergies recorded, followed by injectable medications, which accounted for 21%.

The mean age of patients interviewed was 66 years, and women accounted for 64.9% of patients. Patients reported a median of seven home medications and two drug allergies at baseline. The median number of inpatient admissions was one in the previous 12 months.

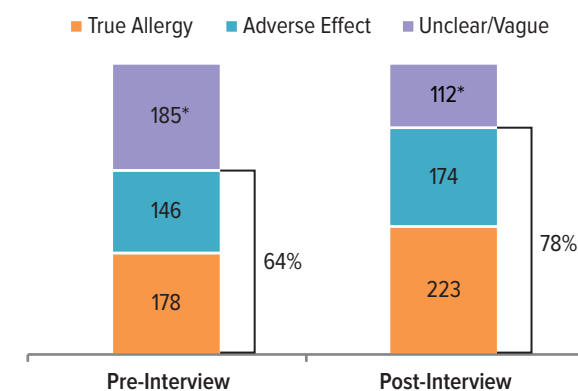
Of the 202 included patients, 123 patients (61%) met the

primary outcome, defined as the need for a clinically relevant change to their drug-allergy history after the standardized drug-allergy questionnaire and interview. Of the 123 patients who met the primary outcome, there were 228 clinically relevant changes made to their allergy histories (average, 1.13 changes per patient) (Figure 3). There were 54 patients (27%) who had at least two changes made to their drug-allergy profile. The most common change made to the patient's allergy history was the addition of a description of the reaction to the reported drug (57% of changes). Updating the description of a previously reported reaction was the next most common

change, which accounted for 60 changes (26%). Removing a previously reported medication from the allergy history occurred 24 times (11% of changes). Adding a medication to a patient's allergy history that was not documented prior to the interview occurred 13 times (6% of changes).

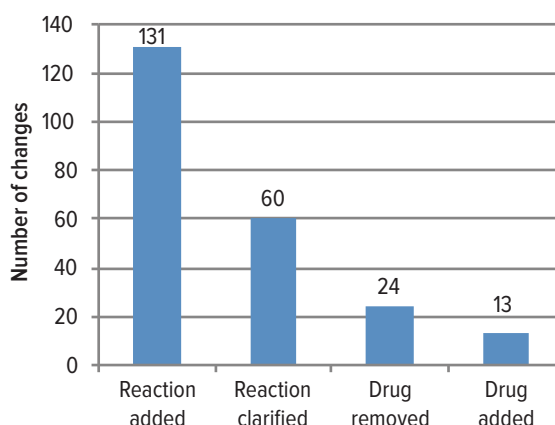
Of the 509 allergies reported, 185 allergies (36%) that had been documented in the medical record prior to the standard-

Figure 2 Drug Allergies per Category



* $P < 0.0001$

Figure 3 Type of Change



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ized drug-allergy questionnaire and interview were categorized as unclear/vague (Figure 2). This was significantly reduced to 112 allergies (22%) after the interview ($P < 0.0001$). Of the patient characteristics investigated, only female gender (RR, 1.6; 95% CI, 1.01–1.69) and greater than three reported drug allergies prior to the interview (RR, 1.31; 95% CI, 1.05–1.62) were significantly associated with the need for a clinically relevant change (Figure 4).

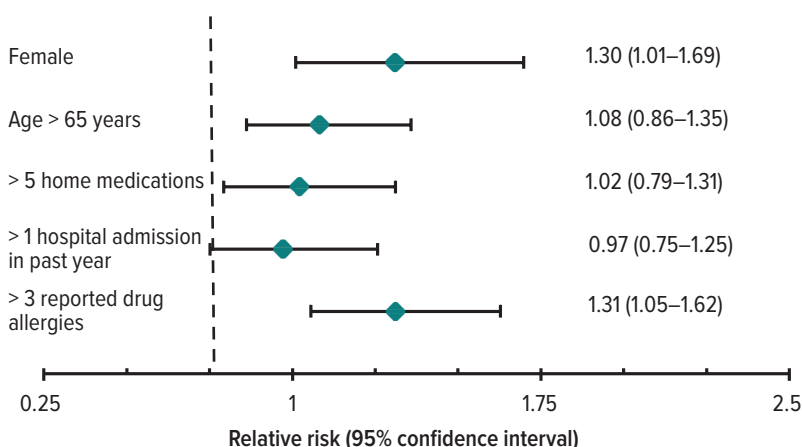
DISCUSSION

This project found that 61% of patients had a need for a clinically relevant change in drug-allergy information after a standardized drug-allergy questionnaire and interview. The number of allergies classified as unclear/vague was significantly lower after the interview compared with the number before. Women and patients with greater than three reported allergies had an approximately 30% higher risk of needing a change in drug-allergy history. One possible explanation for the need to update drug-allergy histories more frequently in patients with greater than three documented drug allergies is that these could actually be intolerances or “adverse effects” rather than “true allergies.” A drug-allergy interview and questionnaire can help distinguish these reactions.

When comparing this project with previous literature that contains a standardized drug-allergy questionnaire and interview component, the results were similar. A previous study showed that after patient interview, 28% of reported allergies could be removed from the patient's record, because the reactions were not considered true allergies as determined by a pharmacist.⁶ Our project found that 11% of allergies could be removed. This number is lower than the previous study most likely due to the conservative approach taken when removing an allergy. An allergy was removed under the following circumstances: if a patient specifically requested the allergy to be removed or if the patient was certain they have never had an allergy to the medication in question. In the previous literature, 40% of reported allergies were not considered to be true allergies as judged by a pharmacist.⁸ The results of this project were consistent with previous literature and found that after a patient interview, 34% of allergies were not consistent with symptoms of a true allergy. This project goes deeper by asking more questions surrounding the allergy instead of simply categorizing the allergy based on perceived severity. This project also looked for specific patient characteristics associated with a need for a clinically relevant change to their drug-allergy history.

There are several areas where these findings may be further developed. There is a great opportunity for all clinicians to identify and correct allergy information. This project could be applied to many kinds of patients, not just those in the hospital. One way this could be done is by making the collection of patient allergy information with subsequent reactions a standard intake protocol for the institution. Our project also identified patients who are at high risk for having an inaccurate

Figure 4 Relative Risk for Clinically Relevant Change



rate or incomplete allergy history. Documenting patients with such characteristics would be a great starting point if it is not feasible for the institution to obtain allergy information on all patients. This project also supports the use of a standardized drug-allergy questionnaire. The questionnaire may not need to be as elaborate as the one used in this project; however, creating a standardized drug-allergy questionnaire may be helpful to guide clinicians in asking specific questions regarding a patient's drug allergies in order to gather more complete information. More complete information could also be obtained if clinicians are required to list a reaction for each allergy. If the reaction is not known, the reaction should be documented as “unknown” to identify that the allergy has been acknowledged.

There are several limitations to this project. The allergy information collected was only as reliable as the information provided by the patient during the interview. Obtaining allergy information directly from the patient was the approach in this project; however, hospitalized patients may have a variety of hindrances that limit their ability to provide accurate and complete information. Patients unable to provide information regarding their allergy histories were not included in this project. However, that is not to say that obtaining allergy information from a patient's caregiver or family would not be beneficial outside of this project. A validated drug-allergy questionnaire that is considered a gold standard tool was unable to be identified and utilized in this project. The questionnaire we used was derived to obtain relevant drug-allergy information in a succinct fashion. There was also a variable time frame from admission to patient interview, although all patients were identified within 48 hours of admission.

CONCLUSION

Administering a standardized drug-allergy questionnaire and interview to collect drug-allergy information allowed for more complete information to be obtained. It may be useful for health care professionals to target patients who were found to be at a higher risk of having inaccurate drug-allergy histories from this project.

The results of this project are consistent with previous literature that found many documented drug allergies are

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not consistent with symptoms of a true allergy and could be removed at the discretion of the pharmacist. Additional research can be conducted with using a standardized drug-allergy questionnaire and interview to obtain more complete drug-allergy information.

REFERENCES

1. Pau AK, Morgan JE, Terlino A. Drug allergy documentation by physicians, nurses, and medical students. *Am J Hosp Pharm* 1989;46(3):570–573.
2. Lin RY. A perspective on penicillin allergy. *Arch Intern Med* 1992;152:930–937.
3. Macy E, Contreas R. Health care use and serious infection prevalence associated with penicillin “allergy” in hospitalized patients: a cohort study. *J Allergy Clin Immunol* 2014;133(3):790–796.
4. Johnson JA, Bootman JL. Drug-related morbidity and mortality. A cost-of-illness model. *Arch Intern Med* 1995;155(18):1949–1956.
5. Cook M, Ferner RE. Adverse drug reactions: who is to know? *BMJ* 1993;307(6902):480–481.
6. Tripp D, Brown G. Pharmacist assessment of drug allergies. *Am J Hosp Pharm* 1993;50(1):95–98.
7. Pilzer J, Burke T, Mutnick A. Drug allergy assessment at a university hospital and clinic. *Am J Health Syst Pharm* 1996;53(24):2970–2975.
8. Cantrill J, Cottrell W. Accuracy of drug allergy documentation. *Am J Health Syst Pharm* 1997;54(14):1627–1629.
9. Geibig CB, Mansur JM, Medema PG, Nold ED. Pharmacy-controlled documentation of drug allergies. *Am J Hosp Pharm* 1991;48(2):260–264. ■